STATE OF NEW MEXICO
COUNTY OF DOÑA ANA
THIRD JUDICIAL DISTRICT COURT

THE STATE OF NEW MEXICO, EX REL. HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff,

v.

STERIGENICS U.S., LLC, SOTERA HEALTH HOLDINGS, LLC, SOTERA HEALTH LLC, AND SOTERA HEALTH COMPANY,

Defendants.

No. D-307-CV-2020-2629

(Judge Beyer)

UNITED STATES' AMICUS CURIAE BRIEF

On April 14, 2021, Plaintiff the State of New Mexico filed an Emergency Motion for Temporary Restraining Order and Preliminary Injunction. This brief is filed in response to the Court's April 22, 2021 order. In its order, the Court asks the United States Environmental Protection Agency (EPA) to provide its views on the issues raised in Plaintiff's motion, including the impact of the doctrine of primary jurisdiction with respect to EPA. With respect to EPA's role, there is no basis in the Clean Air Act, federal regulatory law or in ongoing actions by EPA for this Court to invoke the doctrine of primary jurisdiction to stay or dismiss this action. Additionally, we note that the parties have cited EPA-generated documents in this action, and we clarify the typical function of those documents in the background section below. The United States, in

this brief, does not address the applicability of primary jurisdiction with respect to the role of the New Mexico Environmental Department.

INTERESTS OF THE UNITED STATES

The Environmental Protection Agency administers the Clean Air Act in cooperation with the States. The Clean Air Act is founded on the principle of "cooperative federalism" and envisions a robust role for the States in administering the Clean Air Act. It preserves the application of State tort law. As set forth in this brief, the Environmental Protection Agency has engaged in certain regulatory activities with respect to ethylene oxide, the pollutant at issue in this case. The United States files this brief at the Court's request to clarify the applicable statutory and regulatory framework under federal law and the scope of relevant EPA activities. This filing is limited to addressing applicable provisions of federal law and ongoing federal actions that may be relevant to the Court's decision in this case; and the United States ordinarily does not address issues of state law.

BACKGROUND

I. Statutory and Regulatory Background

A. The Clean Air Act

The Clean Air Act (CAA), 42 U.S.C. §§ 7401-7671q, sets up a comprehensive program for control of air pollution through a system of shared federal and state responsibility. Hazardous air pollutants are "pollutants which present, or may present . . . a threat of adverse human health effects . . . or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise." 42 U.S.C. § 7412(b)(2). The 1990 CAA Amendments established a two-phase approach to control

emissions of hazardous air pollutants. EPA's role is prescribed by statute. The first phase involves EPA setting technology-based emission standards. *Id.* § 7412(d). The second phase requires EPA to determine whether the residual risks that remain warrant more stringent standards. *Id.* § 7412(f). The idea is to set limits that, as an initial matter, require all sources in a category to at least clean up their emissions to the level that their best performing peers have shown can be achieved. *See* 42 U.S.C. § 7412(d)(3). The second phase then returns to a risk-based analysis – which occurs within eight years after initial standards are promulgated – and requires EPA to consider whether residual risks remain that warrant more stringent standards. *Id.* § 7412(f).

CAA section 112(b)(1) lists pollutants to be regulated within industrial source categories. 42 U.S.C. § 7412(b)(1). Ethylene oxide is a listed hazardous pollutant. *Id.* Section 112(c)(1) requires EPA to publish a list of categories of sources emitting listed hazardous air pollutants. *Id.* § 7412(c)(1). A "category" of sources is a group of sources having common features (such as boilers, or coal-fired power plants), suggesting they should be regulated in the same way.

B. EPA's Nationwide Regulation of Ethylene Oxide Commercial Sterilization Facilities

On July 16, 1992, EPA published a list of major and area sources (the source category list) that required the promulgation of section 112 standards. 57 Fed. Reg. 31,576. Ethylene oxide commercial sterilization and fumigation operations were one of the listed categories. *Id.* EPA first published hazardous air pollutant standards for these commercial sterilization facilities more than twenty-five years ago. *See* 59 Fed. Reg. 62,585 (Dec. 4, 1994). As part of this regulatory process, EPA set major source

and area source standards for those facilities. *See Id.* at 62,586. The current ethylene oxide emission standards are available at 40 C.F.R. part 63, subpart O.

The process of ethylene oxide sterilization typically occurs in a sterilization chamber, from which there are three major emission points: (1) the sterilization chamber vent; (2) the aeration room vent; and (3) the chamber exhaust vent. 84 Fed. Reg. 67,892. The sterilization chamber vent evacuates ethylene oxide from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes. *Id.* The aeration room vent evacuates ethylene oxide from the aeration room (where sterilized materials off-gas in a facilitated environment following sterilization). *Id.* The chamber exhaust vent evacuates ethylene oxide-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes. *Id.* In the initial 1994 regulation of ethylene oxide sterilization facilities, EPA regulated all three major emission points. Those regulations were later revised due, in part, to a series of explosions at sterilization facilities. *See* 84 Fed. Reg. 67,892. As a result of those revisions, EPA's regulations currently require no controls for emissions from the chamber exhaust vent. *See* 40 C.F.R. part 63, subpart O.

Ethylene oxide emissions can occur from sources other than the aeration room vent, sterilization chamber vent, or the chamber exhaust vent – such emissions are considered "fugitive emissions."[1] EPA, to date, has not set standards for fugitive

[1] Fugitive emissions are emissions that could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening. *See* 40 C.F.R. §§ 70.2, 71.2 (defining "fugitive emissions" under CAA Title V). For purposes of regulation of ethylene oxide, fugitive emissions are considered to be "those

emissions from ethylene oxide commercial sterilization facilities. 84 Fed. Reg. 67,892. In 2019, however, EPA issued an advanced notice of proposed rulemaking that solicited information to aid in potential future revisions to ethylene oxide emission standards for commercial sterilization facilities. *Id.* at 67,889.

Potential revisions being considered include developing control measures for fugitive emissions as well as promulgating additional safety measures for chamber exhaust vents, and other improvements. *Id.* Since 2019, EPA has issued a questionnaire to nine companies with commercial sterilization facilities, including Sotera Health, under section 114 of the CAA. *See EPA Proposes Info. Collection Request for Ethylene Oxide Commercial Sterilization Facilities,* U.S. EPA (June 5, 2020) https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-updates. The questionnaire was intended to help EPA better understand ethylene oxide emission sources, measurement and monitoring techniques, and available control technologies. EPA has also initiated a proposed information collection request to gather the same information from companies that did not receive the initial questionnaire. *See* 86 Fed. Reg. 24,862 (May 10, 2021, proposed information collection request); 85 Fed. Reg. 35,931 (June 12, 2020, proposed information collection request). This regulatory process is ongoing.

C. EPA's delegation of authority to New Mexico

Congress, in the Clean Air Act, recognizes that air pollution and control is the "primary responsibility of States and local governments." 42 U.S.C. § 7401(a)(3).

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emissions which are not routed to an existing pollution control device." 84 Fed. Reg. 67,894.

Section 112(l) of the CAA and 40 C.F.R. part 63, subpart E authorize EPA to delegate authority for the implementation and enforcement of emission standards for hazardous air pollutants to a state that satisfies the statutory and regulatory requirements in subpart E. 42 U.S.C. § 7412(l); 40 C.F.R. § 63.12(b) (addressing EPA's authority to delegate administration of hazardous air pollutant standards).

EPA has delegated to New Mexico the authority to administer the state's program implementing specified new source performance standards and national emission standards for hazardous air pollutants. 83 Fed. Reg. 46,107 (Sept. 12, 2018). This delegation includes authority to administer standards for ethylene oxide sterilizers. 83 Fed. Reg. 46,112 (showing the delegation status in New Mexico for part 63 standards).

Permits in New Mexico are issued pursuant to New Mexico's Air Quality Control Act and regulations adopted pursuant to that act, including title 20, chapter 2, pts. 72, 77, 78 and 82 of the New Mexico Administrative Code (establishing New Mexico's new source performance standard program and New Mexico's program for national emission standards for hazardous air pollutants). Pursuant to those provisions, and potentially others, New Mexico administers CAA programs relevant to the facility at issue in this case.

II. Factual Background

A. Permitting and allegations concerning the Santa Teresa Facility

Defendants Sterigenics U.S. LLC, Sotera Health Holdings, LLC, Sotera Health LLC, and Sotera Health Company (collectively, Defendants) own and operate an

industrial sterilization and fumigation facility in Santa Teresa, New Mexico.[2] Complaint ¶ 3. At this facility, Defendants use substantial quantities of ethylene oxide. Complaint ¶ 6.

The Santa Teresa facility operates under an Air Quality Bureau New Source Review permit issued by the New Mexico Environment Department. *See* Sterigenics Air Quality Permit, attached as Ex. A to Declaration of Steve Ortiz, Dkt. 14-1 in Civil Action No. 2:20-cv-01355-KG-KRS. This is a "permanently applicable" permit issued in response to a prior modification of the Sterigenics facility. *See* Permit §§ A101-102. While the Sterigenics facility permit addresses some forms of ethylene oxide emissions, it does not address fugitive emissions (though this is not surprising because, as noted above, EPA has not, to date, established fugitive emission standards for ethylene oxide from commercial sterilization facilities). *See* Sterigenics Air Quality Permit.

In this action, New Mexico alleges that Defendants have caused "substantial unreported, uncontrolled releases" of ethylene oxide. Complaint ¶ 19. Allegedly, these uncontrolled releases are due to lax oversight of Defendants' operation, including leaving open sterilization chamber doors, improperly washing equipment, and causing delivery of sterilized products that were off-gassing during the delivery process. *Id.* New Mexico also alleges that mechanical failures and breakdowns led to additional uncontrolled emissions of ethylene oxide. Complaint ¶ 20. All of New Mexico's claims are state-law based tort claims, and are based on alleged harms associated with ethylene oxide emissions. Complaint ¶¶ 53-222. New Mexico has not alleged any

[2] This factual summary is based on factual allegations contained in New Mexico's complaint. The United States has not independently verified the accuracy of those allegations.

federal claims and has not asserted claims based on a violation of the state-issued permit.

B. EPA's Integrated Risk Information System and National Air Toxics Assessment

Both Plaintiff and Defendants cite to an assessment of ethylene oxide carcinogenicity released in 2016 by EPA's Integrated Risk Information System (IRIS). Additionally, the parties cite to EPA's 2014 National Air Toxics Assessment.

EPA's IRIS program identifies and characterizes health hazards posed by chemicals found in the environment. *See Basic Info. About the Integrated Risk Info. Sys.,* U.S. EPA, https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system (last visited June 17, 2021). To the extent that any information presented in its 2016 evaluation of ethylene oxide may be relevant to this action, we note that the EPA assessment focuses generally on potential hazards posed by the substance itself, and not to any factors associated with any individual facility or risk to the population near any specific facility.

EPA's 2014 National Air Toxics Assessment (NATA) was developed as a screening tool for state, local, and tribal air pollution control agencies. *See NATA Overview*, U.S. EPA, https://www.epa.gov/national-air-toxics-assessment/nata-overview (last visited June 17, 2021). This tool helps those agencies identify likely emission sources for pollutants and identify areas that they may wish to study further. *Id.* More localized studies are often needed to better characterize local-level risk. *Id.* The 2014 NATA includes a map application that allows users to display risks, emissions, and other NATA data on a map. A user's guide to the mapping application is available at https://gispub.epa.gov/NATA/2014NATAmapappuserguide.pdf. While useful as a

screening tool, NATA has limitations. *See NATA Limitations*, U.S. EPA, https://www.epa.gov/national-air-toxics-assessment/nata-limitations (listing limitations including data availability) (last visited June 17, 2021).

When EPA becomes aware of a data gap, the agency issues a "NATA Emissions Update," a document that provides a list of some of the issues that either were not addressed during the review of a prior assessment or were not known at the time of a prior assessment. Known data gaps in 2014 NATA have been periodically acknowledged, most recently in a document listing known changes to emissions that occurred after 2014 and prior to July 28, 2020. *See* Ex. M to Sterigenics Preliminary Injunction Opposition. EPA notes in that document that the Santa Teresa facility installed a control device for ethylene oxide between 2014 and 2016.

On March 31, 2020, EPA's Office of the Inspector General issued a Management Alert, which called on EPA to provide information to 25 communities that NATA identified as potentially having the highest risk from ethylene oxide emissions. *See Ethylene Oxide: Technical Reviews and Outreach to Potentially Affected Communities Status Report for Sterigenics – Santa Teresa, NM,* Attached as Ex. L to Sterigenics Preliminary Injunction Opposition. In response to that Management Alert, EPA noted that it believed the Office of the Inspector General "erroneously included the Sterigenics Santa Teresa Facility in its list of facilities for follow-up." *Id.* EPA explained that NATA estimated risks based on 2014 emissions data but that more current emissions data would result in changes in the estimate of risk associated with the Santa Teresa facility. *Id.* EPA noted that it had learned that the Santa Teresa facility installed a pollution control device that reduced ethylene oxide emissions from 2014 levels, and that this

emissions reduction would be expected to reduce risk. *Id.* EPA did not, however, conclude that the data indicates that additional investigation would be inappropriate.

DISCUSSION

Despite the name, the doctrine of primary jurisdiction does not involve jurisdictional questions, but prudential considerations. *Syntek Semiconductor Co., Ltd. v. Microchip Technology Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). It is a common law doctrine used to coordinate administrative and judicial decision making. *Mashpee Tribe v. New Seabury Corp.*, 592 F.2d 575, 580 (1st Cir. 1979). Thus, when a court and an agency have concurrent jurisdiction and "the agency has expertise of a specific sort, a court may grant the agency primary jurisdiction to decide the issue under its enabling statute, before the court becomes involved." § 15:94. Primary jurisdiction, O'Reilly, Administrative Rulemaking (2021 ed.). Primary jurisdiction allows a court to stay further proceedings, or dismiss a case, so as to give parties an opportunity to seek an administrative ruling. *Reiter v. Cooper*, 507 U.S. 258, 268 (1993) (recognizing court's ability to stay a cause pursuant to doctrine of primary jurisdiction); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 761 (9th Cir. 2015) (recognizing court's ability to dismiss pursuant to doctrine of primary jurisdiction). The doctrine should be invoked sparingly, as it often results in "added expense and delay." *Mississippi Power & Light Co. v. United Gas Pipeline Co.*, 532 F.2d 412, 419 (5th Cir. 1976). Not every case that implicates the expertise of federal agencies warrants invocation of primary jurisdiction. Rather, the doctrine is reserved for a "limited set of circumstances" that "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Clark v. Time Warner Cable*, 523

F.3d 1110, 1114 (9th Cir. 2008) (quoting *Brown v. MCI WorldCom Network Servs.*, 277 F.3d 1166, 1172 (9th Cir. 2002)).

While there is no "fixed formula" governing application of the doctrine, in general, the factors that courts evaluate include (1) whether the issue is a question within an agency's particular field of expertise, (2) whether the issue is particularly within the agency's discretion, (3) whether there is a substantial risk of inconsistent rulings, and (4) whether a prior application to the appropriate agency has been made. *See, e.g.*, *United States v. Western Pacific Railroad Co.*, 352 U.S. 59, 62–63 (1956); *Raritan Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011).

There is no pending or completed action by EPA that points to application of the doctrine to the instant case based on any of these factors. First, the legal questions at issue in this case are primarily questions of New Mexico state law, and EPA has no particular expertise regarding New Mexico tort law. In *United States v. Western Pacific*, the Supreme Court examined whether, in order to effectuate the statutory purposes of the Interstate Commerce Act, a reviewing court was required to allow the Interstate Commerce Commission to construe a tariff issue before that same issue was addressed by a reviewing court. 352 U.S. at 65. The Supreme Court focused on whether the particular expertise of the agency was vital to inform the legal question (involving tariff construction and the reasonableness of a tariff imposed on a shipper) presented to the Court of Claims. Concluding that knowledge of "intricate facts" about the transportation sector was necessary to interpret the meaning of the key term at issue in that case and that the Interstate Commerce Commission had the necessary knowledge, the Supreme Court held that the tariff issues involved in this case were initially matters for the

Interstate Commerce Commission to determine. *Western Pacific*, 352 U.S. at 66-69. There is no parallel here.

New Mexico tort law forms the basis of New Mexico's claim here. These questions of state law will be applied to a factual scenario that involves details that will be clarified through discovery. The question of whether Plaintiff can prove that Defendants' emissions caused a harm that is actionable under state nuisance law can be fully addressed by the parties to the action and is a question that can readily be resolved by this Court. EPA does not have any unique expertise necessary to resolve those factual issues. Rather, such actions are standard fare for state trial courts and clearly fall "within the conventional competence of th[ose] courts." *See Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 305–06 (1976) (in an ordinary fraud action against an airline, expertise of the Civil Aeronautics Board, which had concurrent jurisdiction, was not likely to be helpful); *Baykeeper*, 660 F.3d at 691 (state environmental agency's general expertise in environmental matters did not support court's "abdicat[ion of] its responsibility" where Congress had authorized judicial actions over the subject matter of the suit).

With respect to the second factor, EPA does not have "particular" discretion over a New Mexico tort action – in fact EPA has no statutory role to play in such an action. Even if the underlying issue were construed to be fundamentally tied to the enforcement of CAA emission control standards for stationary sources, it is clear that Congress did not provide EPA with "particular" discretion or exclusive control over that subject matter. *See generally Baykeeper*, 660 F.3d at 691–92 (recognizing that, where a state environmental agency may have general discretion over environmental matters, it did

not have "particular" discretion where courts had authority to enforce the federal statutes at issue). Instead, Congress expressly preserved the right of states to take concurrent action. A savings clause of the Clean Air Act captioned "Retention of State Authority" provides:

> Except as otherwise provided ... nothing in this chapter shall preclude or deny the right of any State or political subdivision thereof to adopt or enforce (1) any standard or limitation respecting emissions of air pollutants or (2) any requirement respecting control or abatement of air pollution....

42 U.S.C. § 7416. Consistent with that statutory provision, EPA's regulations recognize that states may adopt air emission standards, limitations, provisions or regulations that are more stringent than federal standards, under specified circumstances. 40 C.F.R. § 63.12(a). Congress contemplated that states would have an independent role to play in controlling air pollution. *See Merrick v. Diageo Americas Supply, Inc.*, 805 F.3d 685, 690-93 (6th Cir. 2015) (concluding that the Clean Air Act did not preempt state common-law claims); *Bell v. Cheswick Generating Station*, 734 F.3d 188, 194-197 (3d Cir. 2013) (same); *Her Majesty the Queen in Right of the Province of Ontario v. Detroit*, 874 F.2d 332 (6th Cir.1989) (holding that the Clean Air Act did not preempt suit under state Environmental Protection Act). Additionally, both EPA and New Mexico have concurrent authority to enforce violations of standards and permits issued by the state under delegated CAA programs. *See* 83 Fed. Reg. 46,107 (delegating to New Mexico authority for implementation and enforcement of relevant emission standards). Finally, Congress contemplated a structure that would allow state and citizen actors to litigate such questions in trial-level courts across the country. 42 U.S.C. § 7604 (citizen suit enforcement provision). Accordingly, EPA lacks "particular" or exclusive discretion over the issues presented in this state nuisance action.

The third factor also weighs against an exercise of primary jurisdiction. "The court in its discretion may defer to an administrative agency in the interests of judicial economy, where the agency is in a better position to fully develop a record of the grievance." *McDowell v. Napolitano*, 895 P.2d 218, 222 (N.M. S. Ct. 1995). Here, however, EPA is not currently engaged in an administrative or judicial enforcement action against Sterigenics with respect to its New Mexico facility and, accordingly, EPA is in no better position to develop the factual record relevant to New Mexico's claims than the parties already before the Court. Additionally, EPA cannot be compelled to file such an action. *Heckler v. Chaney*, 470 U.S. 821 (1985) (recognizing that an agency's decision not to take an enforcement action is not subject to judicial review). Put another way, there are no EPA enforcement actions that could generate rulings that are inconsistent with the rulings of this Court.

With respect to the fourth factor, there has been no "application" to EPA to assess the particular facts of this case. As mentioned in the prior paragraph, EPA has not commenced an administrative or judicial enforcement action with respect to Sterigenics's Santa Teresa facility. Although EPA has issued an advanced notice that it is collecting information in support of a future rule that, if finalized as proposed, could set nationwide regulations for fugitive emissions from ethylene oxide sterilization facilities like the facility at issue in this case, 84 Fed. Reg. 67,889, that ongoing EPA rulemaking process provides no basis for applying the doctrine of primary jurisdiction to this case.

EPA's rulemaking process is still underway, and it could be some time before a final rule is issued. Once issued, that rule might be very different from the proposed

rule. Even if a final rule were issued that provided emission standards for fugitive emissions from stationary sources such as Sterigenics's plant, nothing that will occur in the pending state nuisance action will interfere with, impede or otherwise affect EPA's ability to fulfill its regulatory obligations under the CAA.

For the reasons discussed above, with respect to EPA's role, there is no basis in the Clean Air Act, federal regulatory law or ongoing actions by EPA for this Court to invoke the doctrine of primary jurisdiction to stay or dismiss this action.

Respectfully Submitted,

FRED FEDERICI
Acting United States Attorney

/s/ Manuel Lucero June 25, 2021
MANUEL LUCERO
Assistant United States Attorney
P.O. Box 607
Albuquerque, NM 87103
(505)224-1467
manny.lucero@usdoj.gov

JEAN E. WILLIAMS
Acting Assistant Attorney General
Environment and Natural Resources Division
U.S. Department of Justice

Dated: June 25, 2021

s/ Matthew R. Oakes
MATTHEW R. OAKES
Senior Counsel
Law and Policy Section
Environment and Natural Resources Division
U.S. Department of Justice
P.O. Box 7611
Washington, DC 20044-7611
Phone: (202) 514-2686
Matthew.Oakes@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing *United States' Amicus Curiae Brief* with the Clerk of Court using the Court's electronic filing system.

Dated: June 25, 2021 *s/ Matthew R. Oakes*